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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,715	03/01/2002	Kathleen S. Keegan	27866/37081A/US	7406

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EXAMINER	
PATEL, SUDHAKER B	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,715	KEEGAN ET AL.	
	Examiner	Art Unit	
	Sudhaker B. Patel, D.Sc.Tech.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,8-12,14-19 and 21-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,8-12,14-19 and 21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *7/29/04*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request dated 7/12/04 for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. See interview summary dated 7/29/04 enclosed with this communication. Non-Final action follows.

Together with their earlier amendments, applicants have cancelled claims 4,6,7,13,20, amended claims 1-3,5,8-12,19,21,25,28-30. Therefore, the claims in this application are the claims 1-3,5,8-12,14-19,21-31.

After further review and reconsideration, this application is found not ready for allowance in, as is condition for the reasons stated bellow.

2. ***Examiner's Position:***

Complexity of inventions:

Compound(s) Claims: 19,21-25,29-31 if limited to compounds not overlapping with the rejections stated bellow, and related to invention of Group I would be novel.

However, applicants' method of use claims are not limited to compounds of invention of Group I, but they encompass compounds already patented earlier by different institutions. The instant specification does not clearly and exactly recite that these compounds were included in the protocol for either screening or actual testing.

Method of use Claims: 1-3,5,8-12,14-18 are related to:

(1). A method of inhibiting checkpoint kinase in a generic cell;
(2). A method of sensitizing cells undergoing chemotherapeutic or radio therapeutic treatment for a generic medical condition, wherein a therapeutic amount of the **instantly claimed compound(s)** as well as **compounds already existing as per prior art(s),** is administered **in combination with** a ***chemotherapeutic agent***, a ***radiotherapeurtic agent***, ***one of a cytokine***, l***ymphokine***, ***growth factor***, **other hematopoietic factor** or ***a mixture thereof***.
(3). **COMPOUNDS, composition & a method of use Claims** 19-31 consist of compounds, composition, and their use with different scope than the method of use of compounds of claim 1. Thus, method of use claim 1 consists of compounds already patented in the prior art(s), for which there is not supporting evidence in the specification.

3. ***Election/Restrictions***

This application consists of more than 1 invention. Applicants have elected invention of Group I, and the elected species of compound of Examples 284, 285,287,289 have following meanings for variables in the generic Formula (I) of claim 1:

W (=unsubstantiated)	= Monocyclic, optionally substituted 1,4-diazine core;
Z	= Phenyl (= Aryl) substituted by –O-**Sub**, R27, R28;
Sub	= Alkylene-substituted piperidine;
X1	= -NH-;
-C (=y)-	= -CO-;
X2	= -NH-;
R27/R28	= H or Alkyl.

The restriction/election requirement has been made ***FINAL*** in the earlier Office Action paper dated 12/19/03.

4. ***Claim Objections***

Claims 1-3,5,8-12,14-18 are objected to under 37 CFR 1.75(c), as being of improper (in) dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The elected invention of Group I consists of novel and patentably distinct compounds of this application only, pharmaceutical composition, and a single, definite and exact method of use for a disease.

Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F. 2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2141.02.

Mere use of different starting materials, whether novel or known, in a conventional process to produce the product one would expect therefrom does not render the process and product unobvious. ***In re Kirkhoven (CCPA 1980) 626 F2d 846, 205 USPQ 1069.***

The issues related to rejections made under 35 U.S.C. 112 paragraphs second and first, and already raised in previous office action dated 12/19/03 have not been resolved yet. See rejections bellow.

5. Rejections maintained: Applicants' arguments and remark have been considered, but not found persuasive for the withdrawal of rejections made under 35 U.S.C.112 paragraph second and first for the reasons already stated in earlier office action paper dated 12/19/03.

Claim Rejections - 35 USC § 112

5.1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5.1.1. Claims 19,21-25,28-31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reasons are as stated in earlier office action dated 12/19/03. Following additional reasons also apply.
5.1.2. Claim 19,21 recite definitions of variables W', Z', Y', but the generic Formula is presented as:"W-X1-(C=Y)-X2-Z". Corrections are required.
5.1.3. Claim 19,21 recite W' as a 2-methyl-pyrazine which could be optionally substituted by C1-3 alkylene-N phthalimide core. These structures do not exactly indicate the point of connection to the main core of the Formula. Corrections are required.
5.1.4. Claim 19 recites R8, R9, R10 as:" CN, NC". Since these are the individual groups, a stable group –N=C as a substituent on to W' ring is not possible because the C valence is not satisfied. Correction is required in this application at the places such group is recited.
5.1.5.Claim 19 recites R8, R9, R10 as:" N (R13-COR7". Since R7 is H, an ending bridge/substituent on to a ring as:"-NH-C-OH" is not possible. Correction(s) is required.
5.1.6. Claim 19 recites Q' as:" not presenting a Hydrogen atom". However, the proviso in page 21 lines 21-23 recites:" provided that when Q' is hydro or -OCH3...". Correction(s) is required.
5.1.7. Claim 26 recites:" A method of inhibiting checkpoint kinase 1 in a cell...". This is not acceptable. The claim remains silent about whose and which specific and exact cell? Are blood cells excluded? Are human cells excluded?
5.1.8. Applicants are reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see e.g. In re Van Guens, 988 F. 2d 1181, 26 PSPG 2d 1057 (Ded. Cir. 1991). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26,27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a single, exact and specific method of sensitizing a specific cell in a individual that can be a human undergoing a chemotherapeutic treatment for a single, exact and well defined medical condition, does not reasonably provide enablement for a genetic method of sensitizing a cell in a individual undergoing a chemotherapeutic or radio therapeutic treatment for a medical condition, comprising administering a therapeutically effective amount of a compound of claim 19 in The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Following additional comments together with the reasons for the rejections are already stated in earlier office action dated 12/19/03 apply.

The claims remain silent about the exact step or process of administration, and there are no specific and exact nature of agent(s), patient-dosage regime recited.

6.A. The nature of the invention:

The compounds, pharmaceutical composition(s), and their method of use claim(s) are drawn for pharmacological/biological activities consisting of a method of inhibiting checkpoint kinase 1(Chk1) in a cell in a generic way, which will include human being(s) for inhibition of any disease or disorder or a condition in a generic way. The claims remain silent about an exact, single and specific disease for which the instant invention's compound is to be administered. .

6.B. The state of prior art:

While the state of the art is relatively high with regard to treatment of a medical condition. e.g. specific cancers, the state of art with regard to treating cancer(s) or by a method of inhibiting CHk1 in a cell broadly is underdeveloped. In particular there is no known anticancer agent, which is effective against all cancers. The Carter et al reference clearly teaches that for the forty known anticancer agents, none are effective against all cancers. (See pages 362-365 of Carter et al reference). No such evidence has been presented here.

Thus, the state of prior art is that there is ***no one compound*** that is capable of the inhibition of all the disorders in a mammal. There are many factors to consider for the treatment or inhibition of disorders such as the inhibition or activation of different receptors, the internal environment of the cell and how certain compounds will mediate different pathways.

6.C The predictability or lack thereof in the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the

more specific enablement is necessary in order to satisfy the statue. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognized that in regards to therapeutic and inhibitive effects on any disorder or a medical condition in a human being(s) is dependent on many conditions such as the cells of blood, cells of bone marrow, different cells present in different organs of an individual, the chemical pathways present, what receptors are inhibited or activated and what the internal environment of the cell is.

Hence, in the absence of a showing of correlation among the inhibition activities consisting of the inhibiting Chk1 or a method of sensitizing cell(s) activity in an individual by a combination therapy involving instant compound(s), chemotherapeutic agent, radio therapeutic agent or a mixture thereof, one skilled in the art is unable to fully predict possible results from the administration of the compounds, pharmaceutical composition, in combination thereof as claimed herein.

The nature of pharmaceutical arts is that IT INVOLVES SCREENING IN VITRO AND VIVO TO DETERMINE WHICH COMPOUNDS EXHIBIT THE DESIRED PHARMACOLOGICAL ACTIVITIES which include inhibition of CHk1 in a cell or sensitizing cells. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art is limited.

The facts as provided above do support the need for additional quantity of experimentation, which would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the method of treatment for various medical disorders/conditions related to different organs of a human being.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of instant compounds to treat various condition(s) disorders/diseases related to a method of in habiting checkpoint kinase 1 in a cell.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, *In re Ferens*, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs. Novo Nordisk*, 42 USPQ2nd 1001, 1006.

The Examiner suggests claiming a single and specific disease to be treated, being mindful of the enablement rejection made above. The issue is the correlation between clinical efficacy for disease treatment and applicants' in vivo/vitro testing/assay if any.

MPEP 2164.01(a) states:" A conclusion of lack of enablement means that, based on the evidence regarding each of the factors stated in above mentioned earlier Office Action, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without

undue experimentation. In re Wright, 999F.2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993)". That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

7. New Rejections:

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8A. Claims 19,21-25,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Failli et al (WO 9911621 dated 3/1999, also cited as Chemical Abstract DN: 130:209605). Failli teaches compound with a CAS RN # 221014-16-0(= Thiourea,N-(5-chloro-2-methylphenyl)-N'pyrazinyl-). Instant claims read onto ref.'621 with following instant meanings of the variables of the Formula of claim 19:

W (=unsubstantiated)	= Monocyclic, **optionally substituted** 1,4-diazine core;
Z	= Phenyl (= Aryl) substituted by –O-**Sub**, R27, R28;
Sub	= Alkylene-substituted piperidine;
X1	= -NH-;
-C (=y)-	= -CO-;
X2	= -NH-;
R27/R28	= H;
R7,R8,R9,R10R11,R12	= "optionally substituted" where applicable groups.

The ref.'621 also teaches the utility as anti-atherosclerotics for increasing HDLcholestrol levels.

9A. Claims 19,21-25,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Mabire et al (WO 9929674 dated 6/1999, also cited as Chemical Abstract DN: 131:44827). Mabire teaches compound with a CAS RN # 227282-17-9(= Urea,N-(4-(1-imidazole-1-yl)-2-methylpropylphenyl)-N'pyrazinyl-). Instant claims read onto ref.'674 with above stated imeanings of the variables of the Formula of claim 19. The ref.'674 also teaches the utility as retinoid metabolism inhibitors.

1. Claims 19,21-25,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinisch et al (Archiv der Pharmazie(Weinheim Germany) 330/7,207-210(1997), also cited as Chemical Abstract DN: 128:13243). Heinisch teaches compounds with CAS RN # 198978-70-0(= Urea,N-(2-chloro-6-methylphenyl)-N'pyrazinyl-). CAS RN# 198978-76-6(=Thiourea,N-(2-chloro-6-methylphenyl)-N'pyrazinyl-). Instant claims read onto ref.'621 with above stated meanings of the variables of the Formula of claim 19.

2. Claims 19,21-25,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinisch et al (Magnetic Resonance in Chemistry,35/9,653-655(1997), also cited as Chemical Abstract DN:127:277898). Heinisch teaches compound with a CAS RN # 196699-82-8(= Urea,N-(2,6-dimethylphenyl)-N'pyrazinyl-).CAS RN# 196699-91-9(=Thiourea,N-(2,6-dimethylphenyl)-N'pyrazinyl-). Instant claims read onto ref.'621 with following instant meanings of the variables of the Formula of claim 19.

3. Claims 19,21-25,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Atwal et al (J. Medicinal Chemistry,39/1,304-13(1996), also cited as Chemical Abstract DN: 124:75535). Atwal teaches compound with a CAS RN # 166263-12-3P(= urea,N-(5-cyano-2-t-butyl-phenyl)-N'-pyrazinyl-). Instant claims read onto ref.'621 with following instant meanings of the variables of the Formula of claim 19. The ref. Atwal also teaches the utility as cardioselective Antiischemic ATF-Sensitive Potassium Channel Openers.

4. Claims 19,21-25,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Atwal et al (CA 2132771 dated 4/1995, also cited as Chemical Abstract DN: 123:143653). Atwal teaches compound with a CAS RN # 166263-12-3P(= urea,N-(5-cyano-2-t-butyl-phenyl)-N'-pyrazinyl-). Instant claims read onto ref.'621 with following instant meanings of the variables of the Formula of claim 19. The ref. Atwal also teaches the utility as cardiovascular agents.

5. Claims 19,21-25,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Wisterowicz et al (Acta Poloniase Pharmaceutica,46/2,101-13(1989), also cited as Chemical Abstract DN: 112:216860). Wisterowicz teaches compound with a CAS RN # 71306-90-6(= Thiourea,N-(4-chloro-phenyl)-N'pyrazinyl-).CAS RN # 126994 (=Thiourea,N-(2,6-dichloro-phenyl)-N'pyrazinyl-). CAS RN# 126994-16-9(=Thiourea,N-(2,6-dichloro-phenyl)-N'(3-chloro-pyrazinyl-). CAS RN# 126994-21-6(=Thiourea,N-(2,6-dichloro-phenyl)-N'-3-methoxypyrazinyl-).Instant claims read onto ref.'621 with following instant meanings of the variables of the Formula of claim 19.

6. Claims 19,21-25,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Foks et al (Acta Poloniae Pharmaceutica,35/5,615-18(1978), also cited as Chemical Abstract DN: 91:117865). Foks teaches compound with a CAS RN # 71306-94-0(= Thiourea,N-(2,4-dimethylphenyl)-N'pyrazinyl-).CAS RN# 71306-95-1(=Thiourea,N-(2,5-dimethylphenyl)-N'pyrazinyl-). Instant claims read onto ref.'621 with following instant meanings of the variables of the Formula of claim 19.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Failli et al as applied to instant claims above, and further in view of Chaplin et al(British J. of Cancer ,62(4). 561-6(1990)).

10. Failli teaches the compounds instantly claimed which have 1,4-diazine core. The ref.' differs from the instant method of use claims by having pharmacolological. Activity which is not similar to claimed herein.

11. The other reference, Chaplin et al claims the utility of the 1,4-diazine core as claimed herein.

12. Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to prepare instant compounds by modifying or replacing substituents on to the 1,4-pyrazine ring of either Failli or Chaplin and prepare compounds with side chain(s) as instantly claimed, and try out the use/utility as a pharmaceutical/sensitizer by using the conventional chemistry knowledge. The motivation stems from the expectation of making compounds having equal or better sensitizing agent.

13. Claims 1-31 are also rejeced under 35 U.S.C. 103(a) as being unpatentable over Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Failli et al as applied to instant claims above, and further in view of .Hartman et al(U.S.P. 4609659, dated 9/1986). The ref.'659 teaches compounds with a 1,4-diazine core, and its utility as adjuncts to radiation therapy as claimed herein. See Chemical Abstract DN: 105 226657.

14. The references do not exactly tyeach the instantly claims compounds of invention of Group I, but they do teach the compounds having simpler substituents, which are having utility as claimed herein.

15. Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to prepare instant compounds by modifying or replacing substituents on to the 1,4-pyrazine ring of either Failli or Chaplin or Hartman , and prepare compounds with side chain(s) as instantly claimed, and try out the use/utility as a pharmaceutical/sensitizer by using the conventional chemistry knowledge. The

motivation stems from the expectation of making compounds having equal or better sensitizing agent.

16. ("Structural relationships may provide the requisite motivation or suggestion to modify one compound to obtain another compound(s)"). For example, one compound may suggest its homologue/isomer, because homology/isomer often have similar properties, and therefore, chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties, or merely to satisfy their production goals.

17. Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F. 2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2141.02.

18. It has been held that a prior art disclosed compounds is sufficient to render a prima facie case of obviousness as species falling within a genus. See In re SUSI, 440 F 2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by Federal Circuit in Merck & co. V. Biocraft Laboratories, 847 F 2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir.1989).See In re Dillon 16 USPQ 2nd. 1897, 1923 regarding a prima facie case of obviousness of structurally similar compounds disclosed by prior art" regardless lo the properties disclosed in the inventor's application.

Conclusion

Allowable Subject Matter

19. Claims19,21-25,29-31 related to compounds and their pharmaceutical compositions if limited to novel and distinct invention of Group I wherein W is pyrazine, Z = phenyl, X1/X2 are NH, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and all other rejections, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

20. Method of use claim would also be considered for allowance provided applicants claim a single and specific disease to be treated, and provide further evidence to support the method of use claims, being mindful of the enablement rejections made above.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671.

22. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James O. Wilson at (571) 272-0661.

23. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications. Any inquiry of a general nature or relating to the status of this

application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sudhaker B. Patel, D.Sc. Tech.
July 29, 2004

RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624

MUKUND SHAH
SUPERVISORY PATENT
EXAMINER
ART UNIT 1624/1623